REMARKS/ARGUMENTS

Claims 54-63, 65-68, 70-75, 77-82, 84-90, 92-100, 102-108, 110-136, and 215-230 are pending.

Claims 54, 57, 81 and 99 have been amended. No new matter has been introduced. Applicant believes that claim 57 now complies with 35 U.S.C. 112 with "chemical" removed.

Claims 83 and 101 are canceled with their subject matter added to independent claims 81 and 99, respectively.

Applicant thanks the Examiner for the allowance of claims 117-136, 227 and 228.

Applicant requests reconsideration of the rejections of the other pending claims in view of the following arguments.

Claims 54-63, 65-68, 70-75, 77-80

Applicant respectfully submits that independent claim 54 is patentable over Anderson (US 6,168,948) in view of Nelson (US 5,770,029) and Wilding (US 5,726,026) because, for instance, none of the references discloses or suggests a lysing chamber containing at least one filter that captures the sample components by size exclusion as the sample flows through the lysing chamber. In Anderson, a textured wall 1906 has antibodies 1912 that bind to corresponding cell receptors within the sample. Thus, Anderson teaches a different method for cell capture. Wilding also teaches a different method, capturing cells on a wall surface. Nelson does not teach capturing cells for lysis at all.

The steps recited by Applicant in claim 54 provide important advantages. For example, Applicant's inclusion of a filter in the lysis chamber greatly cheapens and simplifies the method as compared to Anderson's reactive ion etching of protrusions 1908 that must then be functionalized with binding agents 1912. Moreover, Applicant's use of a filter in the lysing chamber and Applicant's forcing a sample volume that is greater than the volume capacity of the lysing chamber to flow through the lysing chamber provides for greater concentration of cells in the lysing chamber than would be possible using the method taught by Anderson. This

concentration of cells in the lysing chamber is important for the detection of analyte, e.g. nucleic acid, that is present in a sample in very low starting copy number.

For at least the foregoing reasons, claim 54 and claims 55-63, 65-68, 70-75, 77-80 depending therefrom are patentable.

Claims 81, 82, 84-90, 92-98 and Claims 99-100, 102-108, 110-116

Applicant has amended claims 81 and 99 to include the subject matter of claims 83 and 101, respectively which the Examiner indicated would be patentable.

For at least the foregoing reasons, claim 81 and claims 82, 84-90, and 92-98 depending therefrom are patentable; and claim 99 and claims 100, 102-108, 110-116 depending therefrom are patentable.

Claims 215-226 and 229-230

Applicant respectfully submits that independent claim 215 is patentable over Anderson (US 6,168,948) in view of Nelson (US 5,770,029) and Wilding (US 5,726,026) taken in view further view of Hansmann (US 5,707,799) and Cantor (US 5,5,795,714).

First, the purpose of Applicant's method is completely different from the purpose of the method shown in Hansmann. Specifically, Applicant recites a method for separating an analyte from a fluid sample and for concentrating the analyte into a volume of elution fluid.

Hansmann describes a device for detecting the presence or amount of analyte in a sample. The device shown in Hansmann is incapable of providing captured material in a volume of elution fluid because it lacks an outlet port positioned to permit flow of a sample or elution fluid through the chamber and out of the body of the device. The purpose of the device described in Hansmann is only to capture and detect analyte, not to separate analyte from a sample and provide a highly concentrated eluant of the material, and the device of Hansmann lacks the physical structure necessary to elute the material. Specifically, the device shown in Hansmann does not include an outlet port for exit of the sample or elution fluid from the body of the device. Hansmann only describes a vent for venting gases from the device. This vent is incapable of permitting flow of the sample and flow of the elution fluid through the chamber and out of the

body of the device. In fact, Hansmann does not even mention elution or elution fluid at all anywhere in the patent, a step explicitly recited by Applicant in claim 215.

Thus, there is no fair teaching that one could elute at all from the structures shown in Hansmann. The whole point of the teaching of Hansmann is to capture and detect analyte, and it is not taught or suggested that it would even be possible to elute from the capture structures. Not only is it not taught to elute in Hansmann, but removal of analyte from the Hansmann structures would ruin detection, the entire point of the Hansmann device. Therefore, it would not be obvious to one skilled in the art to employ the structures disclosed in the reference of Hansmann in the chamber of Nelson for capture and elution of a desired analyte. Even if Nelson mentions elution from enrichment material, there is still no teaching that it would be desirable or even possible to elute captured material from the Hansmann structures, much less that such structures should be freely substituted into the enrichment channel of Nelson for capture and elution. One skilled in the art, upon reading the Hansmann reference, would not even be thinking about using the structures for capture and elution, since there is no teaching of elution in the Hansmann patent, and since the point of the structures is to bind analyte for detection, not let it go.

The Cantor reference mentions that target nucleic acid may be eluted from a probe array by denaturation, e.g., heating above melting temperature. This teaching of Cantor does not instruct or suggest to one skilled in the art to employ the structures of Hansmann in the enrichment channel of Nelson to capture and elute material, nor is it obvious to do so.

For at least the foregoing reasons, claim 215 and claims 216-226 and 229-230 depending therefrom are patentable.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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